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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,840	04/08/2005	James B. Doherty	21260YP	9486
210 7590 05/05/2008 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907				
EXAMINER ANDERSON, REBECCA L				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
05/05/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,840

Applicant(s)

DOHERTY ET AL.

Examiner

REBECCA L. ANDERSON

Art Unit

1626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 9-12 is/are rejected.
- 7) ☒ Claim(s) 1-4 and 9-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date 7/27/07, 4/8/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-12 are currently pending in the instant application. Claims 5-8 are withdrawn from consideration as being for non-elected subject matter. Claims 1-4 and 9-12 are objected. Claims 1, 3, 4 and 9-12 are rejected.

Election/Restrictions

Applicant's election with traverse of Group XVIII, drawn to products of the formula I wherein R₂ and R₃ are independently H, C₁-10 alkyl or (CH₂)_nC₃-8 cycloalkyl; X is (CHR₇)_pCO; Y is CO₉CH₂)_n and Q is N in the reply filed on 11 February 2008 is acknowledged. The traversal is on the ground(s) that the inventions of Groups I-XVIII are related and that there is no additional burden on the Examiner. This is not found persuasive because as can be seen in by the closest prior art identified below, the technical feature corresponding to the claims is not a special technical feature as it fails to define a contribution over the prior art. See for example, intermediate #8, page 11 of US Pre-Grant Publication 20070027188 which reads on the non-elected subject matter of, for example, the instant claim 1. In regards to the burdensome search, the inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application No. 60/424,790 and 60/500,094 fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, claims 1-4 and 9-12 do not find support in the prior-filed applications and the date for prior art purposes is 4 November 2003. Claims 1-3 and 9-12 do not find support in the prior filed applications as, for example, the variables R4 and R5 of the instant claims include SOqC1-6alkyl, COC1-6alkyl and OCF3 which are found nowhere in either prior filed provisional application. Claim 4 does not find support in the prior filed applications as, for example, the 8th listed compound in Table 1 is found nowhere in either prior filed provisional application; the 1st listed compound on page 74 of claim 4 is found nowhere in either prior filed provisional application and the compounds of Table

II are not found in US Provisional Application 60/424790, nor is the last compound of Table II found in US Provisional Application 60/500094.

Claim Objections

Claims 1-4 and 9-12 are objected to as containing non-elected subject matter. Claims 1-4 and 9-12 presented drawn solely to the elected invention of Group XVIII would overcome this objection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 4 and 9-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 6 and 11-14 of copending Application No. 11/630172. Although the conflicting claims are not identical, they are not patentably distinct from each other because conflicting claims 1-3 and 5 generically overlap with applicants' claimed invention and provide preferences towards applicants' claimed compounds. Conflicting claims 11-14 are drawn to pharmaceutical compositions of claim 1 which generically overlaps with applicants' claimed invention. Additionally, conflicting claim 6 claims species which anticipate applicants' claimed invention of claims 1, 3, 4 and 9-12, such as N-butyl-N-ethyl-2-(3-isobutyryl-6-methoxy-1H-indazol-1-yl)acetamide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Closest Prior Art

The closest prior art to applicants' instant elected Group XVIII is found in US Pre-Grant Publication 20070027188, which discloses intermediate #8 on page 11 which reads on the non-elected subject matter of the instant claims, such as claim 1 wherein X

is (CHR7)pCO wherein p is 1 and R7 is hydrogen; Q is O; R2 is absent; R3 is hydrogen; Y is CO(CH2)n wherein n is 0; R6 is C1-10alkyl substituted with 3 groups selected from Ra wherein Ra is F, F and C1-10 alkyl wherein said alkyl is substituted with (CH2)nOH wherein n is 0; and one of R4 and R5 is hydrogen and the other is C1-6alkoxy.

Additionally, Masaharu et al. on the 1449 submitted 27 July 2007 provides compounds which read on the non-elected subject matter of the instant claims, such as claim 1 wherein X is (CHR7)pCO wherein p is 1 and R7 is hydrogen; Q is O; R2 is absent; R3 is hydrogen; Y is CO(CH2)n wherein n is 0; R6 is (CH2)nC6-10aryl wherein n is 0 and the aryl is substituted with one Ra group wherein Ra is Cl; and wherein one of R4 and R5 is hydrogen and the other is C1-6 alkyl (see page 2 of Masaharu et al.).

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Rebecca Anderson/
Primary Examiner, AU 1626*

1 May 2008

Rebecca Anderson
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Art Unit 1626, Group 1620
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